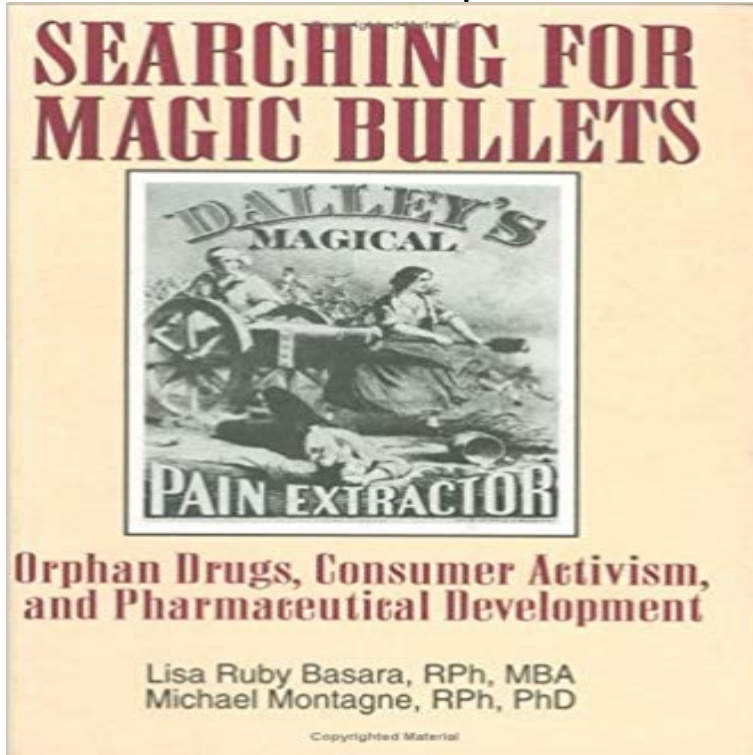


Searching for Magic Bullets: Orphan Drugs, Consumer Activism, and Pharmaceutical Development



Searching for Magic Bullets reveals the quest of consumers, health professionals, and drug developers to find safer and faster methods of bringing new medications to the marketplace. Authors Basara and Montagne explore the current drug development and approval processes, their strengths and weaknesses, and the mechanisms by which patients and organizations evade these processes. Readers learn about the fundamentals of traditional and nontraditional drug discovery and development as they occur in the U.S., as well as the views of consumers, patients, and health professionals. Specific case studies of non-traditional drug development and acquisition strategies are highlighted, including AIDS medications, orphan drugs, and patient importation of medications. Basara and Montagne establish the differences in both knowledge and opinions of health consumers and health professionals regarding drug development, as well as how these differences often lead to frustration, dissatisfaction, and misappropriation of resources. The authors pinpoint the need for consumers and patients to know much more about the discovery and development of medicines, and for health professionals and students to understand patients' concerns, needs and beliefs, including their reasons for considering alternative methods of drug development and acquisition. Searching for Magic Bullets is a springboard from which consumers, health professionals, and students can discuss, debate, and resolve these issues and begin to develop more capable drug development and approval systems. This groundbreaking new book enlightens health professionals about patients' views regarding medication discovery and development and informs consumers and patients about the sometimes conflicting views of health

professionals. It is divided into three sections: drug development and approval in the U.S., a case study of orphan drugs, and risky and sometimes illegal ways in which consumers evade the traditional drug development and approval systems. An Overview of the Chapters: A Review of the Drug Development Process of the Pharmaceutical Industry: Presents the steps that must be taken when researching and developing a new medication. The Food and Drug Administration and the Drug Approval Process: Describes the history and scope of the FDA, the steps involved in acquiring drug approval, and the various stages of clinical testing. Orphan Drug Legislation: A review of the Orphan Drug Act of 1983 and the changes that have recently been proposed by Congress. The impact of the Act is highlighted through a description of products that have been made available since the legislation was enacted. Issues of controversy are also highlighted. Non-traditional Methods of Drug Development: The role of patients and consumers in drug development and evaluation is discussed, with an emphasis on the perceived shortcomings of the formal system. Patient Influence on Drug Development and Regulation: The influence of patient advocacy groups and consumers is discussed in relation to the development and approval of orphan drugs, the fast-tracking of specific medications, and the use of unapproved and alternative therapies. Prescription Drug Importation: Clarifies the current drug importation regulations, as well as provides specific directions for patients wishing to receive such products or learn more about FDA importation laws. The final chapter summarizes safe and rational techniques that empower consumers in their search for beneficial drug therapies. Resources and strategies for obtaining and using information are provided as a reference for readers. A glossary of terms, acronyms, and a directory of supplemental information sources strengthens the readers understanding of the information presented. Who Benefits From This Book?

Consumers and patients can use *Searching for Magic Bullets* as an accurate source of information about significant but often confusing medical issues. The FDA and the way medications are developed are easily misunderstood, while alternative therapies and medication sources are often believed to be the only options. Patients will learn the viewpoints of the pharmaceutical industry, the government, and their health care professionals; the rationale for various steps in the drug development process; the risks and benefits of participation in clinical trials; how to obtain the highest quality care, make informed health decisions, and reduce health care costs; and finally, how to cope with a rare disease and/or limited access to approved medications. The result is an informed, influential, and active patient. For health professionals, this book reviews the steps of drug development and approval and provides explanations for drug development decisions; drug approval time lag; and patient frustrations, misinterpretations, and expectations. It is critical for health professionals to understand the needs of patients and to determine how they can work with patients to find acceptable solutions. The literature references and medical information sources are invaluable in this regard. Pharmaceutical industry executives, product managers, clinical researchers, and sales representatives will find a concise and timely examination of the ways in which medications are discovered, developed, marketed, and used by patients. Discussions of orphan drug development, biotechnology products, and patient issues may also provide new insights into these often misunderstood areas. Pharmacy, medical, nursing, and other students will find this book a consolidated reference source and guidebook for information about the primary issues surrounding drug development and the FDA approval process. Patients' knowledge of alternative medical therapies will only increase and health care curricula must include material that helps students understand

patients' perceptions of the medication development and approval systems, as well as the importance of patients in health care decisionmaking. The disadvantages of current drug development and approval systems are described with the hope that future health professionals can amend these processes and ultimately enhance patient care.

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